



Latin America Regulatory Conference

March 14-16 | Virtual Conference



PROGRAM CHAIR

Maria Guazzaroni Jacobs, PhD

Director, Quality Intelligence, Global Supply
Pfizer Inc

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Director, Regulatory Policy and Intelligence Japan, Emerging
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PROGRAM COMMITTEE

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Regulatory Affairs Senior Director
MSD Panama, Panama

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Latin America Lead, Global Regulatory Policy and Intelligence
The Janssen Pharmaceutical Companies of Johnson & Johnson,
Argentina

Susan Zavala Coloma, MS, RPh

Specialist, Sanitary Evaluation of Pharmaceutical Products,
Biological Products
DIGEMID, Peru

Overview

Join global regulators, industry, and academia to engage in a series of strategic discussions on current regulatory landscape, globalization, and harmonization initiatives in Latin America.

DIA brings you a conference with interactive dynamics, where you will be engaged in discussions with key stakeholders influencing the advancement and implementation of regulatory convergence initiatives in Latin America.

Join us to discuss multi-regional cooperation, global harmonization, and best practices related to Latin America's regulatory landscape. Sessions will highlight regulatory approaches and good practices to ensure reliance in Latin American and strategic initiatives to improve collaboration and cooperation.

**The primary language is English, however simultaneous interpretation in Spanish and Portuguese will be available during this conference.*

Who Should Attend?

Professionals involved in:

- Academia
- Clinical Research and Development
- CROs/Vendors
- Global Submission/Project Management
- Government Affairs
- Medical and Scientific Affairs
- Policy and Intelligence
- Quality Assurance and Compliance
- Regulatory Agencies
- Regulatory Affairs, Operations, and Strategy
- Research and Development
- Strategic Sourcing/Planning



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#LARC22 | DIAGlobal.org

As of March 7, 2022

Schedule At-A-Glance

PRE-EVENT PROMOTIONAL WEBINAR | THURSDAY, FEBRUARY 10

Sessions are held in ET

11:00AM-12:00PM **Forward-Looking to DIA LARC 2022:** Insights from CECMED and Leveraging Lessons Learned from COVID-19

DAY ONE | MONDAY, MARCH 14

Strengthening Regulatory Systems

10:00-11:45AM **Welcoming Remarks and Session 1:** Regional and National Regulatory Updates

11:45AM-12:15PM Break

12:15-1:30PM **Session 2:** Reliance and Good Regulatory Practices

1:30-2:00PM **Session 2 Follow Up:** The Evaluation of National Regulatory Authorities as Tool for Strengthening Regulatory Systems in the Americas

2:00-2:30PM Break

2:30-3:50PM **Session 3:** Regulatory Convergence and Collaboration

DAY TWO | TUESDAY, MARCH 15

Broadening Regulatory Horizons

10:00-11:15AM **Welcome to Day Two and Session 4:** Risk-based Approach in Regulatory Activities

11:15-11:45AM **Session 4 Follow Up:** Transitioning EUA to Full Approvals: Regulatory Perspectives and Lessons for Future Pandemics

11:45AM-12:15PM Break

12:15-1:45PM **Session 5:** Rethinking MedTech and Regulatory Transparency for Medical Devices in the LATAM Region

1:45-2:15PM Break

2:15-3:30PM **Session 6:** E-Labeling and Other Digital Solutions

DAY THREE | WEDNESDAY, MARCH 16

Looking Toward Regulatory Innovation

10:00-11:30AM **Welcome to Day Three and Session 7:** Improving Manufacturing: Lessons from mRNA Vaccines

11:30AM-12:00PM Break

12:00-1:30PM **Session 8:** Orphan Drugs and Advanced Therapies for Rare Diseases: Bringing Transformational Treatments to Patients with Unmet Medical Needs

1:30-2:00PM Break

2:00-3:15PM **Session 9:** A Conversation with the Regulatory Authorities of Regional Reference of the Americas and Closing Remarks

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Distinguish main actions and best practices implemented by health authorities in Latin America and the Caribbean
- Identify current and future regulatory projects and priorities from regulators in the region
- Identify main concepts and uses of Good Regulatory Practices and Good Reliance Practices
- Distinguish the concepts of NRAs of regional reference and of WHO Listed Authorities and identify the roles and responsibilities of reference authorities in the context of the ongoing efforts in strengthening regulatory systems in the Americas
- Distinguish main actions and best practices implemented by the NRAs from Latin America in the past year and lessons learned from COVID-19
- Identify the opportunities offered by convergence in favor of improving transparency and alignment between agencies and industry
- Identify best practices and examples of implementation of risk-based approaches and outline opportunities for the expansion of these approaches in Latin America and the Caribbean
- Recognize the differences and describe the processes between an emergency use authorization and a full approval
- Describe important areas for future development within the medical device industry and recognize the regulatory challenges of medical device registration before and during the pandemic
- Describe traceability and labeling information importance, the synergies supporting regulatory system strengthening, and post-marketing surveillance
- Describe the WHO mRNA vaccines guideline and discuss learnings and opportunities in the Latin America region with respect to vaccines
- Recognize the global and regional regulatory landscape to address rare diseases, identify the unique features and main challenges of cell/gene therapy, and describe the use of RWD and RWE for regulatory decision-making applicable to orphan drugs and advanced therapies

PRE-EVENT PROMOTIONAL WEBINAR | THURSDAY, FEBRUARY 10

11:00AM-12:00PM **Forward-Looking to DIA LARC 2022:** Insights from CECMED and Leveraging Lessons Learned from COVID-19

Session Chair

Viktoria Magyar, LL.M., M.S., Student, USC School of Pharmacy

DIA's Latin America Regulatory Conference (LARC) 2022 virtual Promotional Webinar will provide highlights of the key regulatory concepts and discussions initiatives to be discussed at DIA's LARC 2022 3-day conference occurring held on March 14- to 16, 2022. Gain an insider's view as to what will be discussed at LARC 2022 with a special focus will be on Cuba's National Regulatory Authority (NRA), Center for State Control of Medicines, Equipment and Medical Devices (Spanish acronym CECMED). The Promotional Webinar will touch on lessons learned from the pandemic to achieving a greater regulatory agility and emergency preparedness in the Latin American region.

At the conclusion of this webinar, participants should be able to

- Recognize the key discussion topics to be covered during DIA's 2022 LARC (March 14-16)
- Recognize the impact DIA LARC has on the promotion of regulatory excellence in Latin America and the Caribbean
- Identify the unique regulatory approaches and perspectives that DIA LARC speakers from industry and regulatory agencies have to offer
- Discuss the influence the COVID-19 pandemic has had in shaping the healthcare industry in the Americas with a special focus on CECMED
- Recognize and promote the exchange of regulatory knowledge and experience amongst National Regulatory Authorities (NRAs) and industry in Latin America and the Caribbean

Integration and Strengthening of CECMED's Pending Agenda in the Era of the COVID-19 Pandemic

Olga Lidia Jacobo Casanueva, MSc, Director, CECMED, Cuba

Leveraging Lessons Learned from COVID-19 Pandemic for Greater Regulatory Agility and Emergency Preparedness

Douglas Rodriguez Calderon, MS, Head of LATAM Regulatory Policy, Global Regulatory Policy and Intelligence, Roche Diagnostics, Panama

DAY ONE | MONDAY, MARCH 14

Strengthening Regulatory Systems

10:00-11:45AM

Welcoming Remarks and Session 1: Regional and National Regulatory Updates

Session Chair

Sonia Viejobueno, LLM, Latin America Lead, Global Regulatory Policy and Intelligence, The Janssen Pharmaceutical Companies of Johnson & Johnson, Argentina

Regulatory systems play a crucial role in health systems by ensuring that medicines and other health technologies, including vaccines, blood and blood products, medical devices, among others that are released for the population, are properly evaluated and meet international standards of safety, quality, and effectiveness. This session will gather regulators from Latin America and the Caribbean, who will provide a summary of the progress made on their regulatory projects, take stock of their experiences responding to the COVID-19 pandemic, and describe their plans and priorities for 2022 and beyond.

Moving forward on the Recommendations of the Report on Regulatory Systems Strengthening in the Americas

Maria Luz Pombo, Advisor, Vaccines and Biotechnological Products, Health Systems and Services, Pan American Health Organization (PAHO)

Updates for the Region of Central America

Leonardo Sánchez, PharmD, Director, Agencia de Regulación Sanitaria (ARSA), Honduras

Regulatory Updates for the Region of the Caribbean

Joy St. John, Executive Director, Caribbean Public Health Agency (CARPHA), Trinidad & Tobago

Regulatory Updates for Peru

Ana Gabriela Silva Flor de Olortegui, Executive Director of the Pharmaceutical Products Department, DIGEMID, Peru

11:45AM-12:15PM

Break

12:15-1:30PM

Session 2: Reliance and Good Regulatory Practices

Session Co-Chairs

Susan Zavala Coloma, MS, RPh, Specialist, Sanitary Evaluation of Pharmaceutical Products, Biological Products, DIGEMID, Peru

Cammilla Horta Gomes, MA, MPharm, LATAM Regulatory Policy Lead, Roche, Brazil

Regulatory frameworks and processes that achieve public health objectives, increasingly depend on promoting collaboration, networking, dialogue, trust, and interdependence. This session will gather experts - from international organizations, health authorities, research institutions and industry - to explore international best practices that support transparent, predictable, and consistent regulatory activity, where individual players focus their efforts on where they can add the best value.

Latin American Systems to Enable Reliance: Best Practices and Recommendations

Mario Alanís Garza, Centre for Innovation in Regulatory Science (CIRS), United Kingdom

Experience with Abridge and Verification Reliance Pathways in Saudi Arabia

Nawaf Matar Almutairi, MPharm, Regulatory Affairs Expert, Saudi Food and Drug Authority, Saudi Arabia

Good Regulatory Practices as a Basis for Mature Regulatory Systems

Rebecca Lumsden, PhD, Director, Regulatory Policy and Intelligence, Pfizer Inc., United Kingdom

Panelists

Sandra Ligia González Aguirre, Executive Secretary, Inter-American Coalition for Regulatory Convergence, Advanced Medical Technology Association (AdvaMed)

Maria Teresa Zelaya Lemus, Head of the Drug Registration Unit, Dirección Nacional de Medicamentos de El Salvador, El Salvador

1:30-2:00PM

Session 2 Follow Up: The Evaluation of National Regulatory Authorities as Tool for Strengthening Regulatory Systems in the Americas

Session Co-Chairs

Susan Zavala Coloma, MS, RPh, Specialist, Sanitary Evaluation of Pharmaceutical Products, Biological Products, DIGEMID, Peru

Camilla Horta Gomes, MA, MPharm, LATAM Regulatory Policy Lead, Roche, Brazil

For more than a decade, the Pan American Health Organization (PAHO) has been implementing a regional system for evaluation of National Regulatory Authorities (NRAs) for medicines. This process of evaluation and assessment of NRAs is based on verification of the indicators included in a regionally developed data collection tool, which was based on recommendations from the World Health Organization (WHO). This system has been used to define NRAs of regional reference in the Americas – currently ANMAT, ANVISA, CECMED, COFEPRIS, Health Canada, INVIMA, ISP, and US FDA. The regional data collection tool was the main source used by WHO to create its Global Benchmarking Tool (GBT). This short session aims at providing insights, from PAHO's perspective, on the future of the assessment of NRAs in the Americas, and how the concept of NRA of regional reference will dialogue with the framework for designating and publicly listing WHO-listed authority (WLA).

Moderators

Susan Zavala Coloma, MS, RPh, Specialist, Sanitary Evaluation of Pharmaceutical Products, Biological Products, DIGEMID, Peru

Camilla Horta Gomes, MA, MPharm, LATAM Regulatory Policy Lead, Roche, Brazil

Interviewee

Analia Porrás, Unit Chief, Medicines and Health Technologies, Pan American Health Organization (PAHO)

2:00-2:30PM

Break

2:30-3:50PM

Session 3: Regulatory Convergence and Collaboration

Session Co-Chairs

Roberta Mele Mazza, RPh, RAC, Q&RA Manager, División Diagnóstica, Productos Roche, Argentina

Leonardo Semprun, RPh, Regulatory Affairs Senior Director, MSD Panama, Panama

Regulatory convergence takes many forms and represents an effort to improve the transparency and alignment of interactions between agencies and the industry regarding scientific principles, practices and procedures, as reflected in the acceptance of internationally recognized technical guidance documents and implementation of regulatory mechanisms that align with them. The purpose of this session is to bring together representatives of global regulatory bodies, industry and academia who are directly involved in the management of the regulatory process to exchange knowledge and experiences on the evolving regulatory environment of medical products regarding initiatives of convergence, both regional and international agencies, and understand how it helps streamline the regulatory process to facilitate the achievement of public health goals.

Opportunities for Greater Convergence in Latam

Lawrence Liberti, PhD, RAC, RPh, Adjunct Research Professor, Reg Affairs and Quality Assurance Graduate Program, Temple University School of Pharmacy

Panelists

Overview - Medicines Assessed Under the 'EU-M4all' Procedure

Martin Harvey Allchurch, LLM, Head of International Affairs, European Medicines Agency, Netherlands

Lessons Learned from Collaboration and Convergence Initiatives

Gustavo Mendes Lima Santos, MPharm, General Manager of Medicines and Biological Products, ANVISA, Brazil

Agency Lessons Learned from Collaboration and Convergence Initiatives

Heriberto Garcia Escorza, Director, Instituto de Salud Pública, Chile

Regulatory Convergence - Industry Perspective (Medicines)

Angelika Joos, MPharm, Executive Director, Global Regulatory Policy Merck Sharp & Dohme (Europe) Inc., Belgium

Regulatory Convergence - Industry Perspective (Medical Technology)

Sandra Ligia González Aguirre, Executive Secretary, Inter-American Coalition for Regulatory Convergence, Advanced Medical Technology Association (AdvaMed)

DAY TWO | TUESDAY, MARCH 15

Broadening Regulatory Horizons

10:00-11:15AM

Welcome to Day Two and Session 4: Risk-based Approach in Regulatory Activities

Session Co-Chairs

Cammilla Horta Gomes, MA, MPharm, LATAM Regulatory Policy Lead, Roche, Brazil

Maria Antonieta Tony Roman, MSC, Head Regulatory Policy Emerging Markets LATAM, Novartis, Mexico

This session will open with a presentation on concepts and practices that guide risk-based regulatory activities. A subsequent panel discussion will bring the perspective of regulators and industry on the application of these concepts and practices in GMP inspections, quality control testing, and management of post-approval changes. This session will provide different perspectives and benefits about implementing this important tool, providing a set of information that will contribute to the identification of new opportunities to apply this approach.

From Concept to Practice: Building a Risk-Based Mindset for Regulatory Activities

Hugo Hamel, MBA, MSc, Manager, Radiopharmaceuticals and Monoclonal Antibodies Division, Health Canada

Panelists

Stephan Rönninger, DrSc, Director, Quality External Affairs, Amgen (Europe) GmbH, Switzerland

Raphael Sanchez Pereira, Health and Regulation Expert / Office Manager ANVISA, Brazil

Heriberto Garcia Escorza, Director, Instituto de Salud Pública de Chile

Juan Jose Villegas Campos, GMP Inspector, Laboratory Team of the Inspection and Certification Directorate, DIGEMID, Peru

11:15-11:45AM

Session 4 Follow Up: Transitioning EUA to Full Approvals: Regulatory Perspectives and Lessons for Future Pandemics

Session Co-Chairs

Cammilla Horta Gomes, MA, MPharm, LATAM Regulatory Policy Lead, Roche, Brazil

Maria Antonieta Tony Roman, MSC, Head Regulatory Policy Emerging Markets LATAM, Novartis, Mexico

Some regulatory agencies have established Emergency Use Authorization (EUA) to ensure that potentially lifesaving medical products could be available to people in medical need when there is not an approved and available alternative after demonstrating product effectiveness and that “potential benefits outweigh the known and potential risks”. Products that were granted EUA are expected to transition to full

approvals, offering advantages for the public and pharmaceutical companies. This short session will highlight the FDA experience with accelerated timelines and need for risk-based decision-making during the COVID-19 pandemic, and present lessons that should be considered by regulators in Latin America and the Caribbean in preparation for future health emergencies.

Panelists

Peter Stein, MD, Director, Office of New Drugs, CDER, FDA

Celia Witten, MD, PhD, Deputy Director, Office of the Center Director, CBER FDA

Melissa Torres, Associate Director for International Affairs, CDRH, FDA

11:45AM-12:15PM

Break

12:15-1:45PM

Session 5: Rethinking MedTech and Regulatory Transparency for Medical Devices in the ATAM Region

Session Co-Chairs

Viktoria Magyar, LLM, MSc, Student, USC School of Pharmacy

Roberta Mele Mazza, RPh, RAC, Q&RA Manager, División Diagnóstica, Productos Roche, Argentina

The COVID-19 pandemic has put the medical technology (MedTech) industry at center stage with unprecedented demand for diagnostic test kits and other medical equipment, in addition to extraordinary measures underway to accelerate their manufacturing capabilities. Regulatory flexibility, risk-based approach, remote technologies such as, cloud-based monitoring software, telehealth, and virtual site visits, serve the purpose of optimization of clinical outcomes and patient satisfaction. This session will focus on regulatory challenges of the MedTech industry during and following the pandemic, debate ideas to rethinking the public-health response from a regulator and industry perspective, emphasize the growing relevance of AI/ML-enabled medical devices, and highlight pandemic accelerated digital transformation trends.

Speaker

Ismary Alfonso Orta, Head of Surveillance of Medical Products, CECMED, Cuba

What are the Current and Possible Means of Promoting Transparency of AI/ML-Enabled Medical Devices to Users? What are Important Areas for Future Development?

Nathan Allen Carrington, PhD, Head of Digital Health and Innovation, Global Regulatory Policy and Intelligence, Roche Diagnostics

Regulatory Mechanisms for Software as a Medical Device and the Use of Digital Pathology During the Pandemic

Brandon Gallas, PhD, Research Mathematical Statistician, FDA/CDRH/OSEL/DIDSR

Speaker

Vesa Vuniqi, MS, International Relations Specialist, FDA Latin America Office

1:45-2:15PM

Break

2:15-3:30PM

Session 6: E-Labeling and Other Digital Solutions

Session Co-Chairs

Maria Cristina Mota Pina, MBA, Director, Regulatory Policy and Intelligence - Japan, Emerging Markets, Australia, AbbVie, Inc.

Leonardo Semprun, RPh, Regulatory Affairs Senior Director, MSD Panama, Panama

Nowadays, and especially after the pandemic, it is clear how the world is connected as new tools and technologies emerged to enable patients have access to quality and safe products in an expedited manner. E-labeling and traceability tools are central to support this endeavor. These tools allow that the information needed is accessible to relevant stakeholders (health care professionals, patients, health authorities and industry) in a timely way, allowing them to make sound decisions that leads to better post-marketing

surveillance. In this session the attendees will be able to learn how the evolution of e-Labeling and traceability were catalyzed by the COVID-19 pandemic and how these lessons are applicable to the Latin America region.

Global Landscape

Ronnie Harprit Mundair, Regional Labelling Head - AfME, Canada and LATAM - Senior Director, Pfizer, United Kingdom

Speaker

Rutendo Kuwana, RPh, Team Lead, Incidents and Substandard/Falsified medical products, World Health Organization, Switzerland

Considerations for Implementation and Adoption of Digital Labels Across Latin America

Bruno Di Martino, MBA, PMP, Head, Latin America Regulatory Affairs, Abbvie, Inc

Panelists

Elisa Sulleiro Avendaño, Head of the Registration Procedures Management Division, AEMPS, Spain

Gustavo Mendes Lima Santos, MPharm, General Manager of Medicines and Biological Products, ANVISA, Brazil

DAY THREE | WEDNESDAY, MARCH 16

Looking Toward Regulatory Innovation

10:00-11:30AM

Welcome to Day Three and Session 7: Improving Manufacturing: Lessons from mRNA Vaccines

Session Chair

Maria Guazzaroni Jacobs, PhD, Director, Quality Intelligence, Global Supply, Pfizer Inc

Maria Antonieta Tony Roman, MSC, Head Regulatory Policy Emerging Markets LATAM, Novartis, Mexico

The session will start with a discussion of the WHO guideline on “Evaluation of the quality, safety and efficacy of messenger RNA vaccines for the prevention of infectious diseases: regulatory considerations” which discusses key aspects of manufacture and quality control, and the nonclinical and clinical evaluation of preventive mRNA vaccines for human use. It will also include initiatives to foster COVID19 vaccine production in Latin America. The session will continue with an industry representative who will present the joint industry proposal titled, “Recommendations to Support the Rapid Increase of Manufacturing Capacity for the Production of COVID-19 Therapeutics and Vaccines”, that was submitted to International Coalition of Medicines Regulatory Authorities (ICMRA) and discussed at the ICMRA workshop in July 2021. Finally, lessons learned by the regulators will be highlighted.

Lessons Learned/Opportunities – Related to Vaccine Manufacturing

Connie Langer, MSc, Director, Global CMC, Pfizer Inc.

Tomas Pippo, Advisor, Pharmaceutical Policies and Innovation, Pan American Health Organization (PAHO)

Samuel Simons, Director, Global Regulatory Team Leader, Sanofi

11:30AM-12:00PM

Break

12:00-1:30PM

Session 8: Orphan Drugs and Advanced Therapies for Rare Diseases: Bringing Transformational Treatments to Patients with Unmet Medical Needs

Session Co-Chairs

Maria Antonieta Tony Roman, MSC, Head Regulatory Policy Emerging Markets LATAM, Novartis, Mexico

Sonia Viejobueno, LLM, Latin America Lead, Global Regulatory Policy and Intelligence, The Janssen Pharmaceutical Companies of Johnson & Johnson, Argentina

Orphan Drugs and Advanced Therapies aimed at treating rare and ultra-rare diseases, represent one of the fastest growing sectors in the biopharmaceutical space by offering the promise of personalized treatments for patients with highly unmet medical needs. However, the use of increasingly innovative technologies and regulatory tools, such as real-world data (RWD) and real-world evidence (RWE), also

provides for operational and regulatory challenges during the course of development of these highly complex therapies. In this session, we will discuss the global rare disease landscape and identify existing opportunities for accelerating clinical development with innovative regulatory pathways and the use of modern regulatory tools, including RWE to facilitate development and patient access to orphan drugs and advanced therapies.

FDA Approach to Orphan Rare Diseases and Gene Therapy Development/Industry Perspective

Ilan Irony, MD, Senior Director, Global Regulatory Leader, The Janssen Pharmaceutical Companies of Johnson and Johnson

AT and Orphan Regulatory Pathway in Brazil

João Batista Silva Junior, MHS, RAC, Manager of Blood, Tissues, Cells, Organs Office, ANVISA, Brazil

Role of RWE for Evidence Generation in Rare Diseases/Advanced Therapies

Miriam Fuchs, PhD, Global Therapeutic Area Lead, Reg. Affairs, Oncology Cell and Gene Therapies, Novartis, Switzerland

Post Marketing Activities in Advanced Therapies

Patrick Celis, PhD, Scientific Administrator, European Medicines Agency, Netherlands

1:30-2:00PM

Break

1:30-3:30PM

Session 9: A Conversation with the Regulatory Authorities of Regional Reference of the Americas and Closing Remarks

Session Chair

Maria Cristina Mota Pina, MBA, Director, Regulatory Policy and Intelligence - Japan, Emerging Markets, Australia, AbbVie, Inc.

Pedro Franco, PharmD, PhD, MS, MSc, Director for Global Regulatory & Scientific Policy (GRASP), Merck Serono, United Kingdom

To support regional cooperation, as well as to promote concepts such as regulatory convergence and reliance, the Pan American Health Organization (PAHO) introduced the concept of National Regulatory Authorities of Regional Reference (NRArr). Currently, based on the criteria of a qualification system developed by PAHO, six regulators in Latin America are classified as NRArr, ANMAT, ANVISA, COFEPRIS, CECMED, INVIMA and ISP. Together with the US FDA and Health Canada, these regulators represent the most mature regulatory systems in the region. These regulators are committed to enhance not only their national regulatory practices and procedures, but also to support other regulatory systems in the region in becoming stronger. This panel-style session will represent a guided conversation with key representatives from these NRArr, as an opportunity to further understand their trajectory, lessons learned, current challenges, upcoming plans, and expectations for regional and international cooperation.

Moderators

Maria Cristina Mota Pina, MBA, Director, Regulatory Policy and Intelligence - Japan, Emerging Markets, Australia, AbbVie, Inc.

Pedro Franco, PharmD, PhD, MS, MSc, Director for Global Regulatory & Scientific Policy (GRASP), Merck Serono, United Kingdom

Panelists

Representative Invited, ANMAT, Argentina

Leonardo Dutra, Head of the International Affairs Office, ANVISA, Brazil

Heriberto Garcia Escorza, Director, Instituto de Salud Pública de Chile, Chile

Olga Lidia Jacobo Casanueva, MSc, Director, CECMED, Cuba

Celia Lourenco, PhD, Director General, Biologic and Radiopharmaceutical Drugs Directorate, HPFB, Health Canada

Katherine Marie Serrano, Director, Latin America, Office of Global Policy and Strategy, FDA